UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
LAFAYETTE DIVISION

IN RE: ACTOS (PIOGLITAZONE) PRODUCTS LIABILITY LITIGATION

MDL No. 6:11-md-2299

JUDGE DOHERTY

MAGISTRATE JUDGE HANNA

This Document Applies To:
Allen, et. al. v. Takeda Pharmaceuticals North America, Inc., et al.
(Case No. 12-cv-00064)

MEMORANDUM RULING

This multidistrict litigation arises from product liability claims against the manufacturer and marketer of ACTOS® and other drugs containing pioglitazone. Pending before this Court is a Motion for Partial Summary Judgment [Rec. Doc. 3411] filed by Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals International, Inc., Takeda Pharmaceuticals LLC, Takeda Development Center Americas, Inc., and Takeda California, Inc. (collectively, "defendants").[1] Defendants seek summary judgment on each of the plaintiffs' claims or allegations premised upon a failure-to-warn theory on the basis of federal preemption.[2]

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[1] The Takeda defendants bring this motion broadly as to all Takeda defendants and do not differentiate between them for the purposes of this motion. Additionally, Takeda seeks to extend the outcome of this motion to Eli Lilly, should the Court find that Eli Lilly had responsibility for labeling. Because the instant motion is denied, it is denied as to all defendants on whose behalf it is urged.

[2] Specifically, defendants assert the following causes of action should be dismissed:

- Plaintiffs' Second Cause of Action as Against Defendants (Strict Products Liability - Failure to Warn Claim);
- Allegations contained within each of the following causes of action to the extent they are premised upon a failure to warn:
  - Plaintiffs' First Cause of Action as Against Defendants (Negligence) (allegations relating to "marketing," "promoting," and "packaging" of Actos;
  - Plaintiffs' Fourth Cause of Action as Against the Defendants (Breach of Express Warranty claim);
  - Plaintiffs' Fifth Cause of Action as Against the Defendants (Breach of Implied Warranty for a

The plaintiffs oppose the motion [Doc. 3549], and the defendants have filed a Reply [Doc. 3575]. Defendants have contemporaneously filed a Motion to Strike and Objections to Statement of Material Facts by Plaintiffs in Opposition to Defendants' Motion for Summary Judgement on Preemption. [Rec. Doc. 3576]. This motion is now ripe for consideration. For the reasons set forth below, the Motion for Partial Summary Judgment is DENIED, and the Motion to Strike and Objections to Statement of Material Facts by Plaintiffs in Opposition to Defendants' Motion for Summary Judgement on Preemption is GRANTED IN PART AND DENIED IN PART.

I. Factual and Procedural Background

The following facts are undisputed. In 1989, The Upjohn Company submitted an Investigational New Drug Application (IND) for pioglitazone to the Food and Drug Administration (FDA). The FDA authorized the study of pioglitazone in humans. Upjohn transferred the IND to Takeda in 1995. In January 1999, Takeda submitted a New Drug Application (NDA) for ACTOS®.

Particular Purpose);

- Plaintiffs' Sixth Cause of Action as Against the Defendants (Breach of Implied Warranty of Merchantability);
- Plaintiffs' Seventh Cause of Action as Against Defendants (Fraud and Fraudulent Concealment) (e.g., allegations that Takeda "made material representations by using ... drug packaging and labeling," ... Takeda "lacked sufficient warnings" and Takeda declined to "strengthen Actos' packaging and/or labeling,");
- Plaintiffs' Ninth Cause of Action as Against Defendants (Loss of Consortium).

Additionally, the defendants' motion seeks dismissal of Plaintiffs' Third Cause of Action as Against the Defendants (Strict Products Liability - Defective Design) (allegations that Takeda "labeled in an unsafe, defective, and inherently dangerous condition" and "labeled" a defective product) and Eighth Cause of Action as Against the Defendants (Violation of New York General Business Law Section 349) (allegations concerning "deceptive, inaccurate, false and misleading material information as to the safety of Actos), however, this Court has been notified by the Special Master that the plaintiffs have waived the foregoing claims and do not intend to pursue them.

To the extent defendants argue federal preemption on any claim or allegation that springboards off a failure-to-warn, and because Defendants do not separate the aforementioned claims in their arguments, this Court will address and treat all of the aforementioned claims collectively.

On July 15, 1999, after reviewing Takeda's NDA, and related submissions on ACTOS®, the FDA approved the NDA for ACTOS®, concluding "adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text . . . ."[3]

Prior to FDA approval, Takeda and the FDA engaged in extensive discussions and negotiations regarding the ACTOS® labeling, contained within the "Physician Package Insert" (hereafter "Insert").[4] In the section of the Insert entitled "PRECAUTIONS Carcinogenesis, Metagenesis, Impairment or Fertility," where the label discussed the results of a two-year carcinogenicity study in male and female rats, the FDA required Takeda to add the following sentence: "The relationship of these findings to humans is unclear."

In 2002, prompted by information submitted by another drug manufacturer indicating bladder tumors seen in rats were the result of a mixed peroxisome proliferator activated receptor ("PPAR") class effect, the FDA began discussions with Takeda as to how this information could impact the labeling of ACTOS®. Ultimately, in 2003, the FDA requested that Takeda consider a change in the ACTOS® package insert that would add language regarding the results from 2-year carcinogenicity studies with investigational dual PPAR agonists. After a series of communications, the FDA accepted Takeda's proposal to delete language stating "[t]he relationship of these findings in male rats to humans is unclear" in the Insert, and advised this change could be submitted in the

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[3] *See* Memorandum In Support of Defendants' Motion for Partial Summary Judgment on all Claims for Relief and Allegations Based upon Failure to Warn (Federal Preemption) at p. 6 (hereinafter, "Memorandum in Support").

[4] *See* 21 C.F.R. § 201.57 (1999-2005) and 21 C.F.R. § 201.80 (2006-present).

"Changes Being Effected" (or "CBE") supplement.[5]

After additional negotiations in 2004, Takeda proposed – and the FDA accepted -- the addition of a sentence in the section of the Insert entitled "PRECAUTIONS Carcinogenesis, Metagenesis, Impairment or Fertility" stating: "Urinary tract tumors have been reported in rodents taking experimental drugs with dual PPARα/γ; however, Actos is a selective agonist for PPARγ."[6]

In 2006, concurrent with the FDA's approval of DUETACT,[7] the FDA recommended labeling changes to the "PRECAUTIONS Carcinogenesis, Metagenesis, Impairment or Fertility" section of both the ACTOS® label and the ACTOPLUS MET label. The changes removed the language referencing urinary tract tumors. In its place, the FDA recommended and approved extensive language describing clinical trial findings. Specifically, the proposed language stated:

> In two 3 year studies in which pioglitazone compared to placebo or glyburide, there were 16/3656 (0.44%) reports of bladder cancer in patients taking pioglitazone compared to 5/3679 (0.14%) in patients not taking pioglitazone. After excluding patients in whom exposure to study drug was less than one year at the time of diagnosis of bladder cancer, there were six (0.16%) cases on pioglitazone and two (0.05%) on placebo.[8]

In 2008, the FDA requested Takeda create a Medication Guide[9] for ACTOS® and all other pioglitazon- containing products. Discussions between Takeda and the FDA were ongoing in

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[5] A CBE allows for changes to labeling without prior approval to "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of causal association satisfies the standard for inclusion labeling under 201.57(c)." 21 C.F.R. § 314.70(c)(6)(iii)(A)(2009).

[6] This change was allowed as a "prior approval supplement." "Prior Approval Supplements" require FDA approval before they can be implemented. 21 C.F.R. § 314.70(b)(3) (1999-2005); 21 C.F.R. § 314.70(b)(2)(v)(A) (2006-2013).

[7] DUETACT is a pioglitazone-containing drug, also manufactured by Takeda.

[8] Memorandum in Support, at p.6.

[9] *See* 21 C.F.R. § 208.20 (effective January 1, 2008).

connection with the change to the Medication Guide format until September 9, 2009, when the FDA approved a prior approval supplement for conversion of the Insert to a Medication Guide. The language in the guide was revised to include the following language:

> In studies of pioglitazone (the medicine in ACTOS), bladder cancer occurred in a few more people who were taking pioglitazone than in people who were taking other diabetes medicines. There were too few cases to know if the bladder cancer was related to pioglitazone.

This labeling change essentially parroted the language of the recently approved ACTOPLUS MET XR drug, which was approved in May 2009.

Between November 2010 and August 2011, the labeling of ACTOS® was again revised beginning with the addition of bladder cancer information to the label in the "NONCLINICAL TOXICOLOGY" section and in the Medication Guide, but not in the "WARNINGS AND PRECAUTIONS" section of the new ACTOS® PLR formatted label.[10] However, in August 2011, the FDA approved the labeling with the bladder cancer information in the new "WARNINGS AND PRECAUTIONS" section of the ACTOS® PLR formatted label. This marks the last change in the ACTOS® labeling. It should be noted that the corresponding language in the ACTOPLUS MET, ACTOPLUS MET XR, and DUETACT labels, still in the historical form and not in the new PLR format, is contained in the "PRECAUTIONS" section of those labels.[11]

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[10] *See* 21 C.F.R. § 201.80 (effective June 30, 2006).

[11] Also relevant to this Court's inquiry are the following FDA approvals of pioglitazone-containing products after the FDA approved ACTOS®: On August 29, 2005, the FDA approved Takeda's NDA for another pioglitazone-containing drug, ACTOPLUS MET®. On July 28, 2006, the FDA approved Takeda's NDA for the pioglitazone-containing product called DUETACT®, which led to changes in the labeling of ACTOS®. On May 2009, the FDA approved Takeda's NDA for the pioglitazone-containing drug ACTOPLUS MET XR®, which prompted changes to the ACTOS® labeling. Finally, on January 25, 2013, the FDA approved Takeda's NDA for the pioglitazone-containing drug OSENI.

II. Summary Judgment Standard

A party claiming relief, or a party against whom relief is sought, may move, with or without supporting affidavits, for summary judgment on all or part of the claim. Fed. R. Civ. Proc. 56(a) and (b). Summary judgment is appropriate if "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to a judgment as a matter of law." Fed. R. Civ. Proc. 56(c)(1)(2).

> When a motion for summary judgment is properly made and supported, an opposing party may not rely merely on allegations or denials in its own pleading; rather, its response must – by affidavits or as otherwise provided in this rule – set out specific facts showing a genuine issue for trial. If the opposing party does not so respond, summary judgment should, if appropriate, be entered against that party.

Fed. R. Civ. Proc. 56(e). In general, as summarized by the Fifth Circuit in *Lindsey v. Sears Roebuck and Co.*, 16 F.3d 616, 618 (5th Cir. 1994):

> When seeking summary judgment, the movant bears the initial responsibility of demonstrating the absence of an issue of material fact with respect to those issues on which the movant bears the burden of proof at trial. *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986). However, where the non-movant bears the burden of proof at trial, the movant may merely point to an absence of evidence, thus shifting to the non-movant the burden of demonstrating by competent summary judgment proof that there is an issue of material fact warranting trial. *Id.* at 322; *see also*, *Moody v. Jefferson Parish School Board*, 2 F.3d 604, 606 (5th Cir.1993); *Duplantis v. Shell Offshore, Inc.*, 948 F.2d 187, 190 (5th Cir.1991). Only when "there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party" is a full trial on the merits warranted. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986).
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> The Supreme Court has instructed:
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> [T]he plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial. Where no such showing is made, "[t]he moving party is entitled to a judgment as a matter of law because the nonmoving party has failed to make a sufficient showing on an essential

element of her case with respect to which she has the burden of proof."

Lujan v. National Wildlife Federation, 497 U.S. 871, 884 (1990)(quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986)). The Court later states:

> In ruling upon a Rule 56 motion, "a District Court must resolve any factual issues of controversy in favor of the non-moving party" only in the sense that, where the facts specifically averred by that party contradict facts specifically averred by the movant, the motion must be denied. That is a world apart from "assuming" that general averments embrace the "specific facts" needed to sustain the complaint. As set forth above, Rule 56(e) provides that judgment shall be entered against the nonmoving party unless affidavits or other evidence set forth specific facts showing that there is a genuine issue for trial. The object of this provision is not to replace conclusory allegations of the complaint or answer with conclusory allegations of an affidavit. Rather, the purpose of Rule 56 is to enable a party who believes there is no genuine dispute as to a specific fact essential to the other side's case to demand at least one sworn averment of that fact before the lengthy process of litigation continues.

Id. at 888-89 (1990)(internal quotations and citations omitted). The Fifth Circuit has further elaborated:

> [The parties'] burden is not satisfied with 'some metaphysical doubt as to the material facts,' by 'conclusory allegations,' by 'unsubstantiated assertions,' or by only a 'scintilla' of evidence. We resolve factual controversies in favor of the nonmoving party, but only when there is an actual controversy, that is, when both parties have submitted evidence of contradictory facts. We do not, however, in the absence of any proof, assume that the nonmoving party could or would prove the necessary facts. ...[S]ummary judgment is appropriate in any case where critical evidence is so weak or tenuous on an essential fact that it could not support a judgment in favor of the nonmovant.

Little v. Liquid Air Corp., 37 F.3d 1069, 1075 (5th Cir. 1994) (en banc)(citations and internal quotations omitted).

Finally, in evaluating evidence to determine whether a factual dispute exists, "credibility determinations are not part of the summary judgment analysis." *Id.* To the contrary, in reviewing all the evidence, the court must disregard all evidence favorable to the moving party that the jury is

not required to believe, and should give credence to the evidence favoring the nonmoving party, as well as that evidence supporting the moving party that is uncontradicted and unimpeached. *Roberts v. Cardinal Servs.*, 266 F.3d 368, 373 (5th Cir. 2001).

In evaluating the evidence provided in support of, and in opposition to, a Motion for Summary Judgment, "the court must view facts and inferences in the light most favorable to the party opposing the motion." *Hunt v. Rapides Healthcare Sys. LLC*, 277 F.3d 757, 762 (5th Cir.2001). "A factual dispute precludes a grant of summary judgment if the evidence would permit a reasonable jury to return a verdict for the nonmoving party." *Id.* In evaluating evidence to determine whether a factual dispute exists, "credibility determinations are not part of the summary judgment analysis." *Id.* To the contrary, "in reviewing all the evidence, the court must disregard all evidence favorable to the moving party that the jury is not required to believe, and should give credence to the evidence favoring the nonmoving party, as well as that evidence supporting the moving party that is uncontradicted and unimpeached." *Roberts v. Cardinal Servs.*, 266 F.3d 368, 373 (5th Cir.2001).

III. Legal Analysis

Preemption principles arise under the Supremacy Clause of the U.S. Constitution, which states, "[T]he Laws of the United States ... shall be supreme Law of the Land [.]" U.S. Const., Art. VI, cl. 2. The main premise behind preemption laws is that the historic police powers of the States are not to be superseded by a federal act "unless that was the clear and manifest purpose of Congress." *Wyeth v. Levine*, 555 U.S. 555, 565, 129 S.Ct. 1187, 1194-95, 173 L.Ed.2d 51 (2009).

Preemption comes in three forms. *See English v. Gen. Elec. Co.*, 496 U.S. 72, 79, 110 S.Ct. 2270, 110 L.Ed.2d 65 (1990). First, and the easiest to apply, is express preemption which occurs

when Congress clearly declares its intention to preempt state law. *Id.* Second, implied preemption occurs when the "structure and purpose" of federal law shows Congress's intent to preempt state law. *Id.* Finally, conflict preemption occurs when there is an actual conflict between state and federal law such that it is impossible for a person to obey both. *Id.* The parties agree conflict preemption is the type of preemption at issue in this case. Under conflict preemption, a state law is preempted where it is "impossible for a private party to comply with both state and federal requirements." *English*, 496 U.S. at 79.

Unique to the discussion of preemption in pharmaceutical cases is the notion that there is a dichotomy between the regulation of branded and generic drug labels, with the jurisprudence treating the two differently. A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2674, 180 L. Ed. 2d 580 (2011) *reh'g denied*, 132 S. Ct. 55, 180 L. Ed. 2d 924 (U.S. 2011); *Wyeth v. Levine*, 555 U.S. 555, 570-571, 129 S. Ct. 1187, 1198, 173 L. Ed. 2d 51 (2009); *See also* 21 U.S.C. §§ 355(b)(1), (d). Conversely, a manufacturer seeking generic drug approval is responsible for ensuring that its warning label is the same as the brand name's. *Mensing*, 131 S. Ct. at 2674; *See e.g.*, 21 U.S.C. § 355(j)(2)(A)(v); 21 U.S.C. § 355(j)(4)(G); 21 CFR §§ 314.94(a)(8), 314.127(a)(7).

While the defendants spend a majority of their briefing arguing the specific facts of this case and detailing the numerous discussions and negotiations between Takeda and the FDA concerning the labeling of ACTOS®,[12] the parties appear to agree on one important aspect of the preemption

[12] Defendants offer several arguments in support of their motion for partial summary judgment on all claims based on failure-to-warn, specifically: (a) the FDA's approval of five pioglitazone-containing products is conclusive proof of preemption; (b) "impossibility preemption" bars the plaintiffs' claims concerning the inadequacy of ACTOS's labeling in both 2006 and 2008; (c) federal law preempts claims regarding the inadequacy of labeling after 2003, because the FDA directed defendants to place certain language in the2003 label; (d) federal law preempts plaintiffs' "fraud-on-the-FDA" claims concerning the 2004 label; (e) plaintiffs' claims that the 2004-2011labels are

issue, that is, if the Supreme Court case of *Wyeth v. Levine*, 555 U.S. 555, 129 S.Ct. 1187, 173 L.Ed.2d 51 (2009) applies, the plaintiffs' claims are not preempted. In *Levine*, the plaintiff alleged failure to warn claims against the manufacturer of Phenergan after an intravenous administration of the drug, known as an "IV-push," resulted in gangrene and the amputation of the plaintiff's right forearm. As the defendants do in the instant case, the manufacturer of Phenergan filed a motion for summary judgment, arguing the plaintiffs' failure to warn claims were preempted by federal law. The manufacturer essentially argued it could not have complied with state labeling requirements without violating federal labeling laws. *Levine*, 555 U.S. at 568.

In rejecting the manufacturer's argument, the United States Supreme Court focused on the duties a manufacturer owes under federal labeling laws and the burden associated with establishing a preemption defense. Addressing the numerous discussions and negotiations the parties had had over the years concerning Phenergan's labeling, the Court explained:

> We need not decide whether the 2008 CBE regulation is consistent with the FDCA and the previous version of the regulation, as Wyeth and the United States urge, ***because Wyeth could have revised Phenergan's label even in accordance with the amended regulation***. As the FDA explained in its notice of the final rule, "'newly acquired information'" is not limited to new data, but also encompasses "new analyses of previously submitted data." The rule accounts for the fact that risk information accumulates over time and that the same data may take on a different meaning in light of subsequent developments: "[I]f the sponsor submits adverse event information to FDA, and then later conducts a new analysis of data showing risks of a different type or of greater severity or frequency than did reports previously submitted to FDA, the sponsor meets the requirement for 'newly acquired information.'"

Id. at 569 (emphasis added) (internal citations omitted). Noting the plaintiff had presented "evidence

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inadequate are preempted under current Supreme Court jurisprudence; and (f) plaintiffs' claims are preempted under the "obstacle preemption" principle explained in *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000).

of at least 20 incidents prior to her injury in which a Phenergan injection resulted in gangrene and an amputation," the Court noted, "as amputations continued to occur, Wyeth could have analyzed the accumulating data and added a stronger warning about IV-push administration of the drug." *Id.* at 570. The *Levine* court further noted:

> Of course, the FDA retains authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental application, just as it retains such authority in reviewing all supplemental applications. ***But absent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements.***

Id. at 571 (emphasis added). The *Levine* court explained the mere fact the FDA had approved the drug's label did not suffice; instead, to avail itself of the impossibility preemption defense, the defendant was required to provide "clear evidence" that it had proposed a stronger warning, and the FDA had rejected it. *Id.* at 565, 571-72. Ultimately, the Court held the preemption defense failed where the defendant manufacturer could not prove that it would be "impossible" for defendants to comply with both federal and state requirements regarding the duty to warn, stating:

> Wyeth has offered no such evidence. It does not argue that it attempted to give the kind of warning required by the Vermont jury but was prohibited from doing so by the FDA. . . . We accordingly cannot credit Wyeth's contention that the FDA would have prevented it from adding a stronger warning about the IV-push method of intravenous administration.

Id. at 572.

Similarly, in the instant case, while the defendants advance several factually-based arguments showing much back-and-forth between Takeda and the FDA concerning the labeling of ACTOS®, as in *Levine*, the defendants appear to misunderstand their federal labeling-law duties as they might relate to preemption. The *Levine* court emphasized that despite the many discussions that typically

occur between a drug manufacturer and the FDA about a particular drug's labeling, it remains the duty of the drug's manufacturer to appropriately warn about the potential dangers of the drug, to wit:

> Wyeth suggests that the FDA, rather than the manufacturer, bears primary responsibility for drug labeling. Yet through many amendments to the FDCA and to FDA regulations, ***it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market***. See, e.g., 21 CFR § 201.80(e) (requiring a manufacturer to revise its label "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug"); § 314.80(b) (placing responsibility for postmarketing surveillance on the manufacturer); 73 Fed.Reg. 49605 ("Manufacturers continue to have a responsibility under Federal law ... to maintain their labeling and update the labeling with new safety information").

Id. at 570-71 (emphasis added).

Moreover, as in *Levine*, Takeda does not argue it proposed a stronger warning about the possible link between ACTOS® and incidents of bladder cancer, and the record is devoid of evidence that Takeda, in fact, proposed a stronger warning than the one proposed by the FDA. As the Court noted in *Levine*: ". . . absent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements." *Id.* at 571. Although defendants are correct in stating the labeling language must not deviate from that which was approved by the FDA, defendants still possessed the ability to implement stronger warning language into labeling, by submitting stronger warning language for FDA approval, and/or after FDA approval, by way of a CBE or prior approval submissions. Consequently, this Court concludes the mere fact that the FDA approved, at various times, labeling language proposed by Takeda, such approvals of language do not offer conclusive proof of preemption. More precisely, under the applicable standard set forth in *Levine*, the five approvals by

the FDA of language proposed by Takeda do not serve as "clear evidence that FDA would not have approved a change to [the drug's] label." In short, the plaintiffs have presented evidence of a link between the ingestion of ACTOS and bladder cancer, and the defendants offer no evidence that a stronger warning was proposed by Takeda and rejected by the FDA. Given the lack of such evidence, the Court concludes defendants fail to establish federal preemption in this case. This ruling applies to all of the labels addressed by the moving defendants in their motion.

Defendants' arguments concerning the "Medication Guide" are also unpersuasive. Although defendants agree they could have changed the ACTOS® labeling after initial FDA approval, they argue that once the Medication Guide was utilized in ACTOS® labeling, using the CBE process to change the Insert would have created a conflict between the Insert and the Medication Guide in violation of federal law. This Court does not agree. As the plaintiffs argue, Takeda was involved in lengthy negotiations as to the contents of the language that eventually appeared in the Medication Guide, which Takeda now argues creates a basis for preemption. To the extent there might have been inconsistencies in the different materials constituting the labeling of ACTOS®, such inconsistencies were the responsibility of the defendant manufacturer. As discussed in *Levine*, it remains the duty of the manufacturer to craft and maintain adequate warnings as long as the drug is on the market. 555 U.S. at 570-571.

Moreover, to the extent the defendants attempt to bring this case within the ambit of *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 180 L. Ed. 2d 580 (2011), such arguments are unpersuasive. At issue in *Mensing* were *generic drugs* whose manufacturers had different labeling duties than brand-name manufactures under federal law. A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. *Mensing*, 131 S.Ct. at 2674; *Wyeth*, 555 U.S.

at 570-571; *See also* 21 U.S.C. §§ 355(b)(1), (d). Conversely, a manufacturer seeking generic drug approval, is responsible for ensuring that its warning label is the same as the brand name's. *Mensing*, 131 S.Ct. at 2674; *See e.g.*, 21 U.S.C. § 355(j)(2)(A)(v); 21 U.S.C. § 355(j)(4)(G); 21 CFR §§ 314.94(a)(8), 314.127(a)(7). It is well-settled that generic and brand name drugs are considered under different legal regimes, and the *Mensing* decision, therefore, has no application in the instant case.

Nor are defendants' arguments for the application of the *Buckman*[13] and *Lofton*[14] decisions persuasive. In both *Buckman* and *Lofton*, the court addressed claims of "fraud-on-the-FDA," and as such, are inapposite.[15] At issue here are primarily, and most relevant to this inquiry, failure-to-warn claims based on the alleged inadequacy of the warnings contained in the labeling of ACTOS®. Under the standard announced in *Levine*, under New York law, there is no requirement of a showing of fraud-on-the-FDA to prove the warning in question was inadequate. Furthermore, neither the defendants nor the plaintiffs have cited this Court to any provision or aspect of New York law that is analogous to the fraud-on-the-FDA principles at issue in either *Buckman* or *Lofton*. Therefore, this Court finds defendants' reliance on the preemption principles cited in *Buckman* and *Lofton* to

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[13] *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 353, 121 S.Ct. 1012, 1020 (2001).

[14] *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, 672 F.3d 372 (5th Cir. 2012).

[15] In *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 353, 121 S.Ct. 1012, 1020 (2001), the Supreme Court held federal law preempts state-law causes of action for fraudulent representations to the FDA by a manufacturer. The *Buckman* court reasoned that state fraud-on-the FDA claims are preempted because they "conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives."*Id.* at 350.

In *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, 672 F.3d 372 (5th Cir. 2012) the Fifth Circuit addressed a specific question that involved application TEX. CIV. PRAC. & REM.CODE § 82.007(a)(1). Ultimately, the Fifth Circuit concluded because "§82.007(b)(1) is a fraud-on-the-FDA provision analogous to the claim considered in *Buckman*, we hold that it is preempted by the FDCA unless the FDA itself finds fraud."

be inapplicable to the facts in this case.

Finally, defendants' argument that summary judgment is appropriate under *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 120 S.C.t 1913, 146 L.Ed.2d 914 (2000) is equally unpersuasive. In rendering its ruling in *Levine*, the Supreme Court specifically distinguished the facts of *Geier*, a case in which a governmental agency conducted formal rulemaking and then adopted a plan to phase in a mix of passive restraint devices. In discussing *Geier*, the *Levine* court stated: "Because the plaintiff's claim [in *Geier*] was that car manufacturers had a duty to install airbags, it presented an obstacle to achieving the 'variety and mix of devices that the federal regulation sought. " 555 U.S. at 580, *citing Geier*, 529 U.S. at 881. In discussing the nature of the claims before it, the *Levine* court was unpersuaded that "failure-to-warn claims ... obstruct the federal regulation of drug labeling." *Id.* at 581. Considering that the facts of the instant case are more closely analogous to the facts in *Levine*, and distinguishable from the facts of *Geier*, this Court concludes the *Geier* case is inapplicable in the instant case.

IV. Conclusion

For the foregoing reasons, this Court concludes the defendants fail to satisfy their burden to show they are entitled to the preemption defense under the facts and circumstances of this case. Accordingly, defendants' Motion for Summary Judgement [Doc. 3411] is DENIED.

The "Motion to Strike and Objections to Statement of Material Facts by Plaintiffs in Opposition to Defendants' Motion for Summary Judgement on Preemption" [Rec. Doc. 3576] is DENIED. This Court notes the argument rests upon facts that are not disputed, and the issue of preemption is a purely legal one, and as this Court denies the motion on purely legal grounds – as opposed to factual grounds – this Court concludes the portion of the motion seeking to strike the

plaintiffs' Statement of Facts is not relevant to the inquiry at hand, and is thus, DENIED as irrelevant to the legal inquiry at issue. It is so ORDERED.

THUS DONE AND SIGNED in Lafayette, Louisiana, this 7 day of January, 2014

REBECCA F. DOHERTY
UNITED STATES DISTRICT JUDGE